2015 VFC Requirements

VFC Requirements	Summary
Clinic Key Staff	• All changes in key staff (Primary and Backup Contacts) must be communicated to the Kansas Immunization Program. The named contacts must undergo the program training annually or as replaced. • Training must be documented on "Change of Contact" Form. • Primary and Backup contacts must submit the certificate of completion for "You Call the Shots", *VFC Requirements* and *Storage and Handling* learning modules. • IV 4 must have current list of providers ordering vaccines and provider of record.
Annual Recertification Enrollment	• Update enrollment information and provider profile. • Upload signed VFC Provider Agreement. • Upload requirement training certificates. • 2015 Enrollment are submitted in IV4
Eligibility	• Possess a working knowledge of ALL vaccine funding sources. Use the criteria to screen children prior to administering vaccines. • Document eligibility status at each immunization visit and on keep file for up to 3 years after the date of visit. • Eligibility status must be readily available to staff administering vaccine prior to selecting which vaccine stock to use. • Ensure that children receive the proper funded vaccine. (VFC, CHIP, INSURED).
Billing	• Must adhere to proper billing practices for vaccine administration fees. • Vaccine administration fee for non-Medicaid, VFC eligible children must not exceed maximum $20.26 per dose (CMS state fee cap). Billing should never occur for the cost of VFC vaccine. • VFC-eligible children must not be denied vaccine based on the patient's inability to pay the vaccine administration fee.

Documentation	• Maintain immunization records in accordance with federal law.
	  ○ Name of vaccine
	  ○ Date administered
	  ○ Date VIS was given
	  ○ Publication date of VIS
	  ○ Name of manufacturer
	  ○ Lot number
	  ○ Name and title of person who administered the vaccine
	  ○ Address of clinic where vaccine was administered.
	• Develop, maintain and implement plans for routine and emergency vaccine management. The plans must be reviewed and/or updated annually or more frequently if changes occur. All information in the plan must be current. A "review date" and signature is required on all plans in order to verify that they are current.
	• Have available the most recent publication VIS date for all ACIP recommended vaccines for the population served prior to administering each vaccination.

Vaccine Order	• Reconciliation report must be closed within the past 7 days. • Temperature logs submitted in past 30 days. • Consistent with provider profile on file.

Inventory	• VFC and non-VFC vaccine inventories must be clearly differentiated. (VFC, CHIP, 317, State, Private). • Maintain adequate inventory of vaccine for VFC and non VFC eligible patients. • Vaccine orders must be based off of most recent Provider Profile • Borrowing of vaccine between different funding sources must be a rare, unplanned occurrence. • VFC vaccine cannot be used as a replacement system for privately purchased vaccine inventory. • All instances of borrowing must be properly documented and replaced on the borrowing form.

Storage and Handling	• Dorm/Bar style units are prohibited for vaccine storage
	• MUST have a working calibrated thermometer with a current and valid certificate of calibration testing issued either by an ILAC MRA-accredited laboratory or a certificate that contains the measurement results and a statement indication that it meets ISO 17025 standards. Calibration certificates must contain:
	  • Name of device
	  • Model number
	  • Serial number
	  • Date of calibration
	  • Measurement results indicating the unit passed test and the documented uncertainty of +/-1˚F (0.5˚C)
	• Vaccine must be stored under appropriate temperatures at all times.
	  ○ Refrigerated vaccines
	  35˚-46 ˚ F (2 ˚-4 ˚C)
	  ○ Frozen vaccines
	  -58 ˚F and +5 ˚F
	  (-50 ˚C and -15 ˚C)
	• Thermometer probe must be placed in a central area of the unit directly with the vaccines.
	• Temperature documentation must contain:
	  • At least two temperature readings per day
	  • Time and date of each reading
	  • Name (initials) of the person who assessed and recorded the readings.
	• Must have readily available, a back- up thermometer with a current certificate of calibration. CDC recommends that the backup thermometer be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature reading. The date of calibration testing of the back-up thermometer should be different than the primary thermometer.
	• Must document all excursions and actions taken including the following:
	  • Quarantine and label exposed vaccines
	  • Place vaccine in a unit where it can be stored under proper conditions
	  • Contact KIP
	  • Contact Vaccine manufacturer to obtain documentation of potency
	• Rotate vaccine when a new shipment comes in so that the longer-dated vaccines are stored behind shorter-dated vaccines. If vaccine expires, remove from the storage unit, place in labeled bag.

	"Do Not Use". Expired vaccines must be returned to McKesson within in 6 months of expiration date. • Have sufficient storage space to accommodate vaccine stock at the busiest time of the year without crowding. • Vaccines should be in their original packaging and placed in the middle of the unit, with space both between the vaccine boxes and the side/back of the unit. Vaccines should not be stored in the doors, vegetable bins, or the floor of the unit or under or near cooling vents. Water bottles (refrigerator) or frozen coolant packs (freezer) should be placed throughout each unit to stabilized or extend temperatures during a power outage and serve as physical block to prevent vaccine being exposed to the unit's risk of temperature excursions. • Protect the power source of all vaccine storage equipment by meant of warning labels and back-up generators.
Vaccine Transfers	• Only to another VFC Provider. • Transferred in a qualified pack out container with a data logger.
Administration	• Must offer all ACIP-recommended vaccines for the populations served.
Storage units	• Pharmaceutical grade stand-alone or combination units. • Household/commercial stand-alone units. • Household/commercial combination units using the refrigerator section only.

Digital data loggers	• Detachable probe in buffered material with continuous monitoring and recording capabilities. Easily readable on the outside of the unit.
	• Buffered material include:
	  • Vial filled with liquid(e.g. glycol, ethanol, glycerin)
	  • Vail filled with loose media(e.g. sand. Glass beads)
	  • Solid block of material (e.g. Teflon®, aluminum)
	• CDC *recommends* Data loggers that have the following features:
	  • Alarm for out-of –range temperatures
	  • Current, minimum and maximum temperatures
	  • Low battery indicator
	  • Accuracy of +/-1 ˚F (0.5 ˚C)
	  • Memory stores at least 4,000 readings

Fraud and Abuse	• Provider agrees to operate in a manner intended to avoid fraud and abuse.
	  • Fraud is an intentional deception or misrepresentation made by a person with the knowledge that deception could result in some unauthorized benefit to the practice, person or facility.
	  • Abuse is a practice that is inconsistent with sound fiscal, business, or medical practice which results in unnecessary costs to the Medicaid program.